

REMARKS

Allowed and Allowable Claims

The Applicant thanks the Examiner for the indication that claims 15-23, 41-43, 52, 65 and 67 have been allowed. The Applicant notes that dependent claim 51 depends from allowed independent claim 41. The Applicant presumes that the rejection of dependent claim 51 was an oversight and respectfully requests allowance of claim 51.

Additionally, as set forth on page 4 of the Office Action, claims 54 and 55 have been objected to, but have been indicated as allowable if rewritten in independent form. To that end, claims 54 and 55 have been rewritten in independent form and allowance of the same is respectfully requested.

Claim Rejections – 35 USC §102 and §103

Claims 44-51 and 71 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,599,086 to Doty. Additionally, claim 40 has been rejected under 35 U.S.C. §103(a) as being unpatentable over European Patent No. EP 0179695 to Kehr in view of U.S. Patent No. 6,042,582.

It is well established that “an invention is anticipated if the same device, including all the claim limitations, is shown in a single prior art reference. Every element of the claimed invention must be literally present, arranged as in the claim.” Richardson v. Suzuki Motor Co. Ltd., 9 USPQ.2d 1913, 1920 (Fed. Cir. 1989).

Independent Claim 40

With regard to the rejection of claim 40, the Applicant has amended independent claim 40 to depend from rewritten independent claim 55, which has been indicated as allowable. Accordingly, claim 40 is submitted to be in condition for allowance.

Independent Claim 44 and Dependent Claims 45-47, 49 and 50

Independent claim 44 and dependent claims 45-47, 49 and 50 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,599,086 to Doty. Specifically, the

Office Action refers to the wrench 32 as comprising an elongated drive shaft, the prosthesis 12 as comprising an elongated stem 12, and the retaining plate 66 as comprising upper and lower sections of a transverse flange portion. Even assuming arguendo that the proffered characterization of the wrench 32, the prosthesis 12, and the retaining plate 66 is proper, the Applicant submits that the '086 patent fails to disclose each of the features recited in independent claim 44 for at least the following reasons.

In addition to the comments set forth in response to the previous Office Action is support of the Applicant's position that independent claim 44 is not anticipated by the '086 patent, further reasons support the Applicant's position regarding the patentability of independent claim 44. For example, independent claim 44 has been amended to recite "said elongated driver shaft rigidly connected to the distraction device for application of an external force to the distraction device to transmit said axial force to said one of the adjacent vertebrae". However, as illustrated in Figures 5-7 of the '086 patent and as described in the corresponding portions of the written description, the gear head 34 is freely slid into the axial passage 28 in the prosthesis 12 and intermeshes with the gear teeth 26 on the pins 20, and is rotated to outwardly displace the pins away from the prosthesis 12. However, the intermeshing engagement between the gear head 34 and the gear teeth 26 does not rigidly connect the wrench 32 to the prosthesis 12 in a manner which allows transmission of an axial force to one of the adjacent vertebrae, as recited in independent claim 44. To the contrary, the gear head 34 of the wrench 32 must remain free to slide in an axial direction such that the position of the gear head 34 may be changed from the axial position illustrated in Figure 5 adjacent the pin holes 24 to the axial position illustrated in Figure 6 adjacent the pin holes 25.

For at least the reasons set forth above, the Applicant submits that the '086 patent does not teach each and every element and feature recited in independent claim 44. Therefore, the Applicant respectfully requests withdrawal of the rejection of independent claim 44 as being anticipated by the '086 patent and allowance of the same.

Additionally, claims 45-47, 49 and 50 depend from independent base claim 44. The Applicant submits that dependent claims 45-47, 49 and 50 are patentable for at least the reasons supporting the patentability of independent base claim 44. For example, claim 45 has been

amended to recite that “said transverse stop element is formed integral with said stem portion and together define a single-piece, monolithic structure”, and claim 46 has been amended to recite that “said flange portion is formed integral with said stem portion and together define a single-piece, monolithic structure”. The retaining plate 66 and the prosthesis 12 are clearly not formed integral with one another such that together they define a single-piece, monolithic structure. Instead, the retaining plate 66 comprise individual components that are formed separately from one another, and clearly do not define a single-piece, monolithic structure. Specifically, as illustrated in Figure 7, the retaining plate 66 is attached to the prosthesis 12 via machine screws 68.

Additionally, claim 50 recites that “said elongated driver shaft is threadedly engaged with said stem portion”. Even assuming arguendo that the wrench 32 comprises an insertion tool, and that the prosthesis 12 comprises a stem portion, the wrench 32 is clearly not in any way “threadedly engaged” with the prosthesis 12. Indeed, the only contact between the wrench 32 and the prosthesis 12 is the engagement of the gear head 34 with the gear teeth 26 on the pins 20. However, the intermeshing engagement between the gear head 34 and the gear teeth 26 clearly does not constitute threading engagement, and the ‘086 patent fails to even suggest threading engagement between any portion of the wrench 32 and the prosthesis 12.

Independent Claim 48

As set forth on page 2 of the Office Action, independent claim 48 has been rejected as being anticipated by the ‘086 patent to Doty. Specifically, the Office Action refers to the wrench 32 as comprising an elongated drive shaft, the prosthesis 12 as comprising an elongated stem 12, and the retaining plate 66 as comprising upper and lower sections of a transverse flange portion.

In addition to the comments set forth in response to the previous Office Action is support of the Applicant’s position that independent claim 48 is not anticipated by the ‘086 patent, further reasons support the Applicant’s position regarding the patentability of independent claim 48. For example, even assuming arguendo that the wrench 32 comprises an insertion tool, and that the retaining plate 66 comprises a transverse flange portion, the retaining plate 66 is not “formed integral with” the wrench 32, as recited in independent claim 48. To the contrary, the

wrench 32 and the retaining plate 66 comprise individual components that are formed separately from one another. Indeed, as illustrated in Figure 7, the retaining plate 66 defines an opening for passage of the gear head 34 therethrough for engagement with the gear teeth 26 on the pins 20. The wrench 32 does not even appear to come into significant contact with the retaining plate 66, much less being formed integral therewith, as recited in independent claim 48. Accordingly, the retaining plate 66 is clearly not formed integral with the wrench 32. If the rejection of independent claim 48 is maintained, the Applicant respectfully requests an explanation as to how the retaining plate 66 is formed integral with the wrench 32 to arrive at the presently claimed invention.

Nevertheless, in order to facilitate prosecution of the subject application, the Applicant has amended independent claim 48 to recite “said flange portion formed integral with said insertion tool and together define a single-piece, monolithic structure”. The retaining plate 66 and the wrench 32 are clearly not formed integral with one another to define a single-piece, monolithic structure. Instead, as discussed above, the wrench 32 and the retaining plate 66 comprise individual components that are formed separately, and clearly do not define a single-piece, monolithic structure.

For at least the reasons set forth above, the Applicant submits that the ‘086 patent does not teach each and every element and feature recited in independent claim 48. Accordingly, the Applicant respectfully requests withdrawal of the rejection of independent claim 48 as being anticipated by the ‘086 patent and allowance of the same.

Independent Claim 71

The Applicant submits that the Office Action does not set forth the entire basis for the rejection of independent method claim 71 as being anticipated by the ‘086 patent. In particular, there is no indication in the Office Action regarding any disclosure in the ‘086 patent that teaches the steps of “selectively engaging” a surgical instrument “comprising a tubular sleeve” with an axial stem portion, and “advancing a surgical device through the tubular sleeve toward the intervertebral space”. Indeed, the Office Action does not make reference to any element in the ‘086 patent that corresponds to a tubular sleeve which is engaged to an axial stem portion, nor

does the Office Action make reference to an element that corresponds to a surgical device which is advanced through a tubular sleeve. Additionally, the Applicant has thoroughly reviewed the '086 patent and can find no reference whatsoever to engaging "a tubular sleeve" with an axial stem portion, and "advancing a surgical device through the tubular sleeve toward the intervertebral space".

Nevertheless, in order to advance prosecution of the subject application, the Applicant has amended the preamble of independent claim 71 to recite a method for performing a surgical procedure on adjacent vertebrae "having a spondylolisthesis condition wherein one of the adjacent vertebrae is anteriorly offset relative to the other of the adjacent vertebrae", and to further recite the action of "transmitting an axial reduction force to the anteriorly offset vertebra to reduce the spondylolisthesis condition". The Applicant notes that these same amendments were incorporated into independent claim 67 in response to the previous Office Action, with independent claim 67 having been allowed.

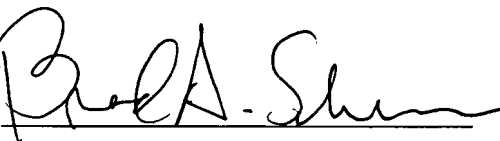
The Applicant has reviewed the '086 patent and submits that there is no teaching or suggestion of performing a surgical procedure on adjacent vertebrae having a spondylolisthesis condition wherein one of the adjacent vertebrae is anteriorly offset relative to the other. Moreover, there is no teaching or suggestion in the '086 patent that the spinal implant is used to reduce a spondylolisthesis condition via engaging a transverse flange portion against an anteriorly offset vertebrae and transmitting an axial reduction force to the anteriorly offset vertebra. Accordingly, the Applicant respectfully requests withdrawal of the rejection of independent claim 71 and allowance of the same.

CONCLUSION

In view of the foregoing remarks, it is respectfully submitted that the Applicant's application is in condition for allowance with pending claims 15-23, 39-52, 54, 55, 65, 67 and 71.

Reconsideration of the subject application is respectfully requested. Timely action towards a Notice of Allowability is hereby solicited. The Examiner is encouraged to contact the undersigned by telephone to resolve any outstanding matters concerning the subject application.

Respectfully submitted,

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